UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CONNETICS CORPORATION and STIEFEL RESEARCH AUSTRALIA PTY. LTD.	) Civil No. 08CV2230
	) FILED: APRIL 18, 2008
Plaintiffs,	) JUDGE MORAN
	) MAGISTRATE JUDGE VALDEZ
v.	)
	)
PENTECH PHARMACEUTICALS, INC.	) JURY TRIAL DEMAND
	)
Defendant.	)
_____	)

ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Plaintiffs, Connetics Corporation and Stiefel Research Australia Pty, Ltd. (collectively "Connetics"), for their Complaint against Defendant Pentech Pharmaceuticals Inc. ("Pentech"), allege as follows:

1. Connetics Corporation is a Delaware corporation having a principal place of business at 3160 Porter Drive, Palo Alto, California 94304. Connetics Corporation is a wholly-owned subsidiary of Stiefel Laboratories, Inc., a Delaware corporation having a principal place of business at 255 Alhambra Circle, Suite 1000, Coral Gables, Florida 33134.

RESPONSE: Defendant is without sufficient information as to the truth of the allegations of Paragraph 1 and, therefore, denies those allegations.

2. Stiefel Research Australia Pty, Ltd. ("Stiefel Australia") is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court, Rowville, Victoria 3168, Australia. Stiefel Australia is a wholly-owned subsidiary of Stiefel Laboratories, Inc.

RESPONSE: Defendant is without sufficient information as to the truth of the allegations of Paragraph 2 and, therefore, denies those allegations.

3. On information and belief, Pentech is a corporation organized under the laws of the State of Illinois, having its principal place of business at 3315 West Algonquin Road, Suite 310, Rolling Meadows, Illinois 60008.

RESPONSE: Admitted.

JURISDICTION AND VENUE

4. This lawsuit is a civil action for patent infringement arising under the patent laws of United States, 35 U.S.C. §§ 271(e)(2)(A), and 21 U.S.C. § 355, et seq.

RESPONSE: Admitted.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271 (e)(4)(B) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESPONSE: Paragraph 5 calls for a legal conclusion to which no response is required, to the extent a response is required, admitted.

6. There exists an actual, justifiable case or controversy between Connetics and Pentech, as to which Connetics requires: (i) a declaration of rights by this Court, and (ii) injunctive relief against Pentech, to prohibit Pentech from continuing to violate applicable laws and regulations to Connetics' irreparable injury, as complained of herein.

RESPONSE: Paragraph 6 calls for a legal conclusion to which no response is required. However, it is admitted that Defendant has committed a "highly artificial" act of infringement, under the statutory scheme of the Hatch-Waxman Act, by the mere filing of an ANDA with a

paragraph IV certification. Defendant denies the remaining allegations of Paragraph 6.

7. Venue is this judicial district is proper pursuant to 28 U.S.C. § 1391(b)-(c) and/or 1400(b). Personal jurisdiction over Pentech in this judicial district is also proper.

RESPONSE: Venue is a legal conclusion to which no response is necessary, to the extent a response is required, admitted.

COUNT I - INFRINGEMENT OF U. S. PATENT NO. 6,126,920

8. On October 3, 2000, United States Patent No. 6,126,920 ("the '920 Patent"), entitled "METHOD OF TREATING A SKIN DISEASE WITH A CORTICOSTEROID-CONTAINING PHARMACEUTICAL COMPOSITION," was duly and legally issued to Medeva Europe PLC as assignee of the inventors named therein. A true and correct copy of the '920 Patent is attached to this Complaint as Exhibit 1.

RESPONSE: Admitted that the '920 patent issued on October 3, 2000 as entitled, otherwise denied.

9. On or about June 25, 2003, Medeva Europe PLC assigned all rights, title and interest in the '920 Patent to Connetics Australia Pty, Ltd.

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 9 and, therefore, denies those allegations.

10. On or about March 26, 2007, Connetics Australia Pty, ltd. changed its name to Stiefel Research Australia Pty, Ltd. Since that time, Stiefel Australia has been and is the assignee and owner of the '920 Patent.

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 10 and, therefore, denies those allegations.

11. Connetics Corporation is the owner of an approved New Drug Application under Section 505(b) of the Federal Food Drug and Cosmetic Act (the "FFDCA" or the "ACT"), 21 U.S.C. § 355(b)(1), for OLUX® Clobetasol Propionate Foam 0.05%, which is covered by the '920 Patent.

RESPONSE: Defendant is without sufficient information and belief as to the allegations of Paragraph 11 and, therefore, denies those allegations.

12. Pentech has filed with the Food and Drug Administration an Abbreviated New Drug Application ("ANDA") pursuant to § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of clobetasol propionate foam 0.05% product. In its ANDA, Pentech includes a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act alleging that the '920 Patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the Pentech's clobetasol propionate foam 0.05% product (a so-called "Paragraph IV Certification"). Pentech's ANDA was assigned ANDA No. 90-133.

RESPONSE: Admitted.

13. On March 6, 2008, Connetics Corporation received from Pentech a letter titled "Certification of Non-Infringement of United States Patent Nos. 6,126,920" in which Pentech informed Connetics Corporation that it had filed ANDA No. 90-133

containing a Paragraph IV Certification with respect to the '920 Patent. Stiefel Australia received an identical communication on March 11, 2008.

RESPONSE: Admitted that Defendant provided Plaintiffs with proper Notice pursuant to Section 505(j)(2)(B)(i) and (ii) and, upon information and belief, said notice was received by Plaintiffs.

14. Because Pentech seeks approval of ANDA No. 90-133, and with such approval seeks to engage in the manufacture, use, offer for sale, or sale of a clobetasol propionate foam 0.05% covered by the '920 Patent before the expiration date of the '920 Patent, Pentech has infringed one or more claims of the'920 Patent pursuant to 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Paragraph 14 calls for a legal conclusion to which no response is required. However, it is admitted that Defendant has committed a "highly artificial" act of infringement, under the statutory scheme of the Hatch-Waxman Act, by the mere filing of an ANDA with a paragraph IV certification. Defendant denies the remaining allegations of Paragraph 14.

15. Pentech's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate foam 0.05% product described in ANDA No. 90-133 will also infringe, directly or indirectly, one or more claims of the '920 Patent.

RESPONSE: Denied.

16. Thus, Connetics is entitled to the relief provided by 35 U.S.C. § 271(e)(4).

RESPONSE: Denied.

17. Upon information and belief, Pentech's infringement of the ‘920 Patent is willful and deliberate with full knowledge of Connetics' rights in the ‘920 Patent, rendering this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied. The filing of this baseless claim for an exceptional case is violation of Rule 11 of the Federal Rules of Civil Procedure.

AFFIRMATIVE DEFENSES

1. The ‘920 patent would not be infringed by Defendant’s commercial manufacture, use, offer for sale, and/or sale of its product covered by ANDA No. 90-133.

2. Plaintiffs have failed to state a claim upon which relief may be granted.

3. The ‘920 patent would not be infringed by a product made in accordance with ANDA No. 90-133.

4. The ‘920 patent is invalid under one or more provisions of 35 U.S.C. § 101, *et seq.*

6. The ‘920 patent is invalid under 35 U.S.C. § 102.

7. The ’920 patent is obvious over the prior art under 35 U.S.C. § 103 and, thus invalid.

WHEREFORE, Defendant requests that this Honorable Court:

(a) Deny Plaintiffs all requested relief and dismiss the Complaint with prejudice.

(b) Order that the effective date of the approval of Defendant's ANDA No. 90-133 is immediate under § 505(j) of the Federal Food and Cosmetic Act, 21 U.S.C. § 355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA.

(c) Declare that the ‘920 patent is not infringed and would not be infringed by Defendant’s commercial manufacture, use, offer for sale, and/or sale of its product covered by ANDA No. 90-133.

(d) Declare that the ‘920 patent is invalid.

(e) Defendant further requests that this Court award its attorneys' fees, costs and all other relief this Court deems just.

COUNTERCLAIMS

1. Defendant, Counterclaim-Plaintiff, incorporates by reference herein its Answer and Affirmative Defenses to the Complaint.

THE PARTIES

2. Counterclaim-Plaintiff Pentech is a corporation organized under the laws of the State of Illinois, having its principal place of business at 315 West Algonquin Road, Suite 310, Rolling Meadows, Illinois 60008.

3. On information and belief, Counterclaim-Defendants, Connetics Corporation is a Delaware corporation having a principal place of business at 3160 Porter Drive, Palo Alto, California 94304.

4. On information and belief, Connetics Corporation is a wholly-owned subsidiary of Stiefel Laboratories, Inc., a Delaware corporation having a principal place of business at 255 Alhambra Circle, Suite 1000, Coral Gables, Florida 33134.

5. On information and belief, Stiefel Research Australia Pty, Ltd. ("Stiefel Australia") is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court, Rowville, Victoria 3168, Australia.

6. On information and belief, Stiefel Australia is a wholly-owned subsidiary of Stiefel Laboratories, Inc.

7. On information and belief, Counterclaim-Defendants allege that they are the owner of U.S. Patent No. 6,126,920 ("the '920 patent"), including the right to sue and collect damages.

8. On information and belief, Steifel Australia is the owner by assignment of all right, title and interest in the U.S. Patent No. 6,126,920, including the right to sue and collect damages.

JURISDICTION AND VENUE

9. These counterclaims constitute an action for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202, and arise under the Patent Laws of the United States, Title 35, United States Code.

10. This Court has jurisdiction of these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and the Patent Laws of the United States, Title 35, United States Code.

11. In the Complaint, Counterclaim-Defendants allege that they are the owner of the '920 patent and allege that Counterclaim-Plaintiff has infringed the '920 patent.

12. As evidenced by the Complaint and this pleading in response thereto, an actual controversy exists between the parties with respect to the alleged infringement of the '920 patent.

COUNT I

13. The '920 patent is not infringed.

COUNT II

14. The '920 patent would not be infringed by a product made in accordance

with ANDA No. 90-133 and would not be infringed by Defendant's commercial manufacture, use, offer for sale, and/or sale of its product covered by ANDA No. 90-133.

COUNT III

The '920 patent is invalid under one or more provisions of 35 U.S.C. § 101, *et seq.*

COUNT IV

18. The '920 patent is invalid under 35 U.S.C. § 102.

COUNT V

19. The '920 patent is obvious over the prior art under 35 U.S.C. § 103 and, thus, is invalid.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff requests that this Honorable Court:

(a) Deny Counterclaim-Defendants all requested relief and dismiss the Complaint with prejudice.

(b) Adjudge and decree that the '920 patent is not infringed and would not be infringed by Counterclaim-Plaintiff's commercial manufacture, use, offer for sale, and/or sale of its product covered by ANDA No. 90-133.

(c) Adjudge and decree that the '920 patent is invalid.

(d) Order that the effective date of the approval of Pentech's Abbreviated New Drug Application (ANDA) No. 90-133 is immediate under § 505(j) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA.

(e) Award Counterclaim-Plaintiff its attorneys' fees, interest and costs.

(f) Grant such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

Counterclaim-Plaintiff requests a jury trial on all issues so triable.

Respectfully submitted,

By: /s/ Robert B. Breisblatt

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of May, 2008, a true and correct copy of the **ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** is being mailed, via first class mail postage prepaid in an envelope addressed to:

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